

## REMARKS

### Sequence Listing

Applicants note that SEQ ID NO:2 and SEQ ID NO:4 of the Sequence Listing originally filed with the application inadvertently contained incorrect sequences. According to the specification at p. 6, lines 1-8, SEQ ID NO:1 is a polynucleotide sequence that encodes the amino acid sequence of SEQ ID NO:2, and SEQ ID NO:3 is a polynucleotide sequence that encodes the amino acid sequence of SEQ ID NO:4. The original SEQ ID NOs: 2 and 4 appear to represent a three letter code amino acid sequence produced by the computer program Patent In from the three letter amino acid sequence encoded by SEQ ID NOs: 1 and 3, respectively, which was inadvertently read by the program as a single letter code amino acid sequence.

Applicants are currently submitting a substitute sequence listing as an uploaded text file that includes the corrected amino acid SEQ ID NOs encoded by SEQ ID NOs: 1 and 3. No new matter is introduced, since the specification teaches that the SEQ ID NOs: 2 and 4 are encoded by the SEQ ID NOs: 1 and 3, respectively.

Additionally, Applicants have noted that Figures 1-3 as originally filed include 16 sequences that were not included in the original Sequence Listing. The currently submitted substitute sequence listing includes the sequences from the figures as SEQ ID NOs: 84 – 99. The figures are likewise amended to include the sequence identifiers. Thus, replacement figures are submitted herewith. No new matter is presented in either the replacement drawings or substitute sequence listing, since support is found in the original drawings.

### Claim objections

The Office objects to claims 1, 12-23, 25, 26 and 29-39 for containing non-elected subject matter. Claims 1, 25 and 29 are currently amended to delete those sequences directed to the non-elected inventions. Applicants reserve the right to pursue the subject matter that has been deleted in another or other applications for patent.

Applicants request that the Office withdraw its objection of the claims in view of the amendment.

### Rejections under 35 USC § 112 – 2<sup>nd</sup> paragraph

Claims 1-3, 12-23, 25, 26 and 29-39 stand rejected as being allegedly indefinite. The Office contends that the claims are vague and indefinite in their use of the phrase 'codon 18'. The Office contends that it is unclear which nucleotides of SEQ ID NO:1 that codon represents, (Office action, p. 3, lines 12-13).

Claims 1, 25 and 29 are currently amended to provide that codon 18 is "codon 18 of SEQ ID NO:1". SEQ ID NO:1 is a 1110 nucleic acid long nucleotide sequence that encodes a PorA

polypeptide and which begins with an ATG (codon 1, which encodes Met) and ends with a TTC (codon 370, which encodes Phe). The specification at p. 15, line 25 – p. 16, line 6 and Table 1 at p. 17 describes codon 18 of SEQ ID NO:1 as being ATC and encoding isoleucine, which is residue number 18 of SEQ ID NO:2, which is encoded by SEQ ID NO:1. One of ordinary skill in the art is well versed in the meaning of codon (triplet nucleic acid sequence encoding a single amino acid) and would reasonably know that codon 18 of SEQ ID NO:1 is the 18<sup>th</sup> nucleic acid triplet along SEQ ID NO:1, starting at position 1.

Based on the amendment and discussion provided above, it should be clear what codon 18 represents in the claims. Applicants request that the Office remove this rejection against the claims.

The Office further alleges that claim 1 is “vague and indefinite because it recites a ‘method for increasing the levels of a *Neisseria* PorA protein or polypeptide in a host cell’ yet there do not appear to be any active steps for increasing the expression”, (Office action, p. 3, lines 15-17).

Claim 1 is currently amended to replace the phrase “method for increasing the expression levels of a *Neisseria* PorA protein” with the phrase “method for expressing a *Neisseria* PorA protein”. Claim 1 is further amended to recite the step of “expression” at step (b). Support for these amendment can be found, e.g., at p. 16, line 4 of the specification. No new matter is presented in this amendment.

Based on the amendments, Applicants believe that the fulfills the requirements of 35 USC § 112, 2<sup>nd</sup> paragraph. Applicants request that the Office withdraw its rejection of the claim under that section.

The Office rejects claim 3 as vague and indefinite for its use of the phrase “isolated from *N. meningitides*”, since the claimed polynucleotide contains a mutated codon 18. Claim 3 is currently canceled, rendering the rejection of the claim moot.

The Office further alleges that claims 1, 2 and 25 are vague and indefinite “due to the phrase ‘other than an ATC codon’”.

Claims 1, 25 and 29 are currently amended to provide the codons TAC, ATT and TTC as the options for codon 18 of SEQ ID NO:1. Claim 2 is currently amended to provide tyrosine and phenylalanine as the options for residue 18 of SEQ ID NO:2. Support for these amendments can be found, e.g., at p. 15, lines 28 – 33 and Table 1, p. 17 of the specification. No new matter is presented in these amendments.

In view of these amendments, Applicants request that the Office withdraw its rejection of the claims under this section.

The Office rejects claim 39 for its use of the term “polynucleotide”, which the Examiner alleges has no antecedent basis. Applicants traverse and assert that the term “polynucleotide” derives its basis from claim 29. Claim 39 claims a host cell of claim 34, which recites the vector of claim 29, which in turn recites the polynucleotide of SEQ ID NO:1, thus providing the antecedent basis for “polynucleotide”.

Applicants respectfully request the Office to withdraw its rejection of claim 39 under 35 USC § 112, 2<sup>nd</sup> paragraph.

Rejections under 35 USC § 112 – 1<sup>st</sup> paragraph (enablement)

Claims 1-3, 13-23, 25, 29 and 31-39 are rejected under 35 USC § 112, 1<sup>st</sup> paragraph as allegedly lacking enablement. The Office alleges that the claims are “unpredictable as to which nucleic/amino acids could be removed and which could be added [at the codon/residue 18 position] with a reasonable expectation of success”, (Office action, p. 5, lines 14-17).

Claims 1, 2, 25 and 29 are currently amended to provide the codons TAC, ATT and TTC as the options for codon 18, and tyrosine and phenylalanine as the options for residue 18. Support for this amendment can be found, e.g., at p. 15, lines 28 – 33 and Table 1, p. 17 of the specification. No new matter is presented in this amendment.

Applicants believe that the claims as amended as discussed above are enabled. Applicants request that the Office withdraw its rejection of the claims under 35 USC § 112, 1<sup>st</sup> paragraph (enablement) in view of this amendment.

Rejections under 35 USC § 112 – 1<sup>st</sup> paragraph (written description)

Claims 1-3, 13-23, 25, 29 and 31-39 are rejected under 35 USC § 112, 1<sup>st</sup> paragraph as allegedly failing to comply with the written description requirement. The Office alleges that the “specification has not set forth any other sequences which would provide for the function of increasing expression levels of porA protein”, (Office action, p. 8, lines 8-9).

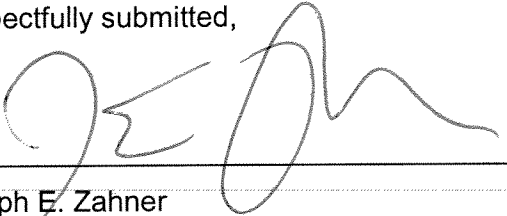
Claims 1, 25 and 29 are currently amended to provide the codons TAC, ATT and TTC as the options for codon 18 of SEQ ID NO:1. Claim 2 is currently amended to provide tyrosine and phenylalanine as the options for residue 18 of SEQ ID NO:2. Support for these amendments can be found, e.g., at p. 15, lines 28 – 33 and Table 1, p. 17 of the specification. No new matter is presented in these amendments.

The claims as amended are described in the specification as filed. Applicants request that the Office withdraw its rejection of the claims under 35 USC § 112, 1<sup>st</sup> paragraph (written description) in view of this amendment.

### CONCLUSION

In view of the foregoing, Applicants believe that all rejections have been overcome and claims 1, 2, 12-23, 25, 26 and 29-39 are in a condition for allowance. The Examiner is invited to call the undersigned agent to discuss any remaining issues.

Respectfully submitted,



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